DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

Injectable or Implantable Dosage Form New Animal Drugs; Euthanasia Solution; Technical Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a supplemental new animal drug application (NADA) filed by Schering-Plough Animal Health Corp. and a supplemental abbreviated new animal drug application (ANADA) filed by Delmarva Laboratories, Inc. The supplemental applications add environmental warning statements to product labeling.

DATES: This rule is effective [*insert date of publication in the* **Federal Register**].

FOR FURTHER INFORMATION CONTACT: Mohammad I. Sharar, Center for Veterinary Medicine (HFV–216), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0159; e-mail: *msharar@cvm.fda.gov.*

SUPPLEMENTARY INFORMATION: Schering-Plough Animal Health Corp., 1095 Morris Ave., Union, NJ 07083, filed a supplement to NADA 119–807 for BEUTHANASIA–D–SPECIAL Solution and Delmarva Laboratories, Inc., 1500 Huguenot Rd., suite 106, Midlothian, VA 23113, filed a supplement to ANADA 200–071 for EUTHASOL Solution. The supplemental applications provide for the addition of environmental warning statements to product labeling. The

supplemental applications are approved as of May 2, 2003, and the regulations are amended in § 522.900 (21 CFR 522.900) to reflect the approvals.

In addition, the agency has found that the regulations do not reflect the 1996 change of sponsorship (61 FR 5505, February 13, 1996) of NADA 128–967 for REPOSE Euthanasia Solution from Syntex Animal Health, Division of Syntex Agri-business, Inc., to Fort Dodge Animal Health, Division of Wyeth. At this time, § 522.900 is revised to reflect that change of sponsorship and a current format.

The agency has determined under 21 CFR 25.33(d)(1) that these actions are of a type that do not individually or cumulatively have a significant effect on the human environment. Therefore, neither environmental assessments nor environmental impact statements are required.

This rule does not meet the definition of ''rule'' in 5 U.S.C. 804(3)(A) because it is a rule of ''particular applicability.'' Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

List of Subjects in 21 CFR Part 522

Animal drugs.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under the authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 522 is amended as follows:

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 522 continues to read as follows:

Authority: 21 U.S.C. 360b.

■ 2. Section 522.900 is revised to read as follows:

§ 522.900 Euthanasia solution.

(a) *Specifications*. Each milliliter (mL) of solution contains:

(1) 390 milligrams (mg) of pentobarbital sodium and 50 mg phenytoin sodium.

(2) 400 mg secobarbital sodium and 25 mg dibucaine hydrochloride.

(b) *Sponsors*. See sponsors in § 510.600(c) of this chapter:

(1) Nos. 000061 and 059079 for use of product described in paragraph (a)(1) of this section.

(2) No. 000856 for use of product described in paragraph (a)(2) of this section.

(c) *Special considerations*. Product labeling shall bear the following warning statements: ''ENVIRONMENTAL HAZARD: This product is toxic to wildlife. Birds and mammals feeding on treated animals may be killed. Euthanized animals must be properly disposed of by deep burial, incineration, or other method in compliance with state and local laws, to prevent consumption of carcass material by scavenging wildlife.''

(d) *Conditions of use in dogs*—(1) *Indications for use*. For humane, painless, and rapid euthanasia.

(2) *Amount*. One mL per 10 pounds of body weight.

(3) *Limitations*. Do not use in animals intended for food. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Dated: July 7, 2003.

Clifford Johnson,

Director, Office of Surveillance and Compliance, Center for Veterinary Medicine.

[FR Doc. 03–????? Filed ??–??–03; 8:45 am]

BILLING CODE 4160–01–S